

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

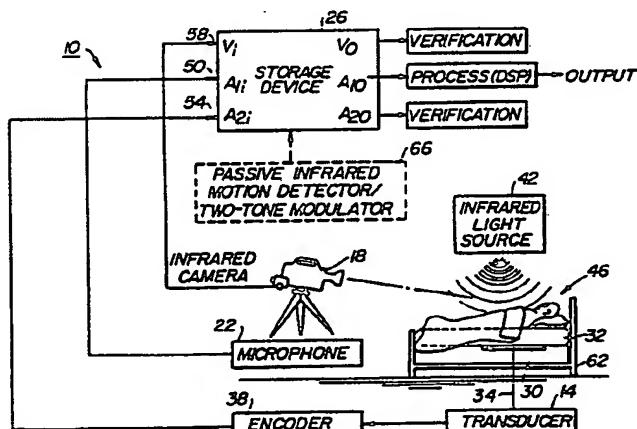
THIS PAGE BLANK (USPTO)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 5/103		A1	(11) International Publication Number: WO 91/15997 (43) International Publication Date: 31 October 1991 (31.10.91)
(21) International Application Number: PCT/US91/02707	(22) International Filing Date: 19 April 1991 (19.04.91)	(74) Agents: FRANKFORT, Howard, M. et al.; Darby & Darby, 805 Third Avenue, New York, NY 10022 (US).	
(30) Priority data: 510,936 19 April 1990 (19.04.90) US		(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent).	
(71) Applicant: CLINICAL TECHNOLOGIES ASSOCIATES, INC. [US/US]; 5 Westchester Plaza, Elmsford, NY 10523 (US).			
(72) Inventors: STEINER, Solomon, S. ; Old Wagon Drive, Mt. Kisco, NY 10459 (US). ALBALA, Bruce, J. ; 104 Ridgefield Avenue, South Salem, NY 10590 (US). FELDSTEIN, Robert ; 1396 Park Lane, Pelham, NY 10803 (US).		Published <i>With international search report.</i>	

(54) Title: INFORMATION PROCESSING SYSTEM FOR COUNTING COUGHS



(57) Abstract

A system using audio and visual information to count coughs or evaluate other discrete information, including respiration and heart rate, relating to a patient in a fixed location such as a bed (46) is disclosed. The system provides movement- and sound-based information derived from the patient's activities to a storage device (26) and subsequently to a signal processing apparatus. One embodiment of the invention includes a pressure transducer (14), a video camera (18), a directional microphone (22), and a videocassette recorder (VCR) having two audio channels. Signals obtained from the transducer (14) and microphone (22) are transmitted to the two audio channel inputs of the VCR, while movement of the patient is recorded using the video camera (18) connected to the video channel input of the VCR. Part or all of the information stored using the VCR may be transmitted to signal processing equipment and frequency filtered to determine the presence and number of coughs, and any remaining information (e.g. the video data) may be used to confirm the count. Because various conditions manifest themselves in movements having different frequency characteristics, the present system, as appropriately modified, also can be used to determine the presence of symptoms such as restlessness and thereby evaluate the effectiveness of medicines such as sedatives and hypnotics.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TC	Togo
DE	Germany	MC	Monaco	US	United States of America

INFORMATION PROCESSING SYSTEM FOR COUNTING COUGHS

This invention relates to a system using movement-
15 and sound-based information to count coughs or evaluate other
discrete activities of a patient.

Background of the Invention

Coughing, or the sudden, forcible expulsion of air at
20 high velocity, is invariably accompanied by sounds having
selected frequency characteristics and differing intensities.
Patients with persistent nocturnal coughs frequently complain
of sleep disruption caused by the cough reflex, as do those
25 capable of hearing the oft-unpleasant sounds associated with
the coughs, including parents of acutely or chronically ill
children. To both the patient and those in close proximity,
therefore, suppression of the patient's cough reflex is
frequently highly desirable. This desirability has led to
30 experimentation with a wide variety of substances as antitus-
sive agents, with the experimentation itself causing a parallel
effort to develop methods for accurately and uniformly deter-
mining the effectiveness of these medications.

Early attempts at artificially inducing coughing with
chemical irritants or using subjective responses in ascertain-
35 ing effectiveness have been largely unproductive and widely
criticized. Artificially inducing coughs leads to increasingly
inaccurate measurements as patients develop tolerances to the
irritants, while varying the frequency and intensity of the

coughs as a function of the concentration of the irritant and the interval between exposures. Although subjective responses may provide valuable evidence of patients' beliefs as to effectiveness, they lack readily quantifiable information 5 useful for comparing the wide range of competing antitussives. In addition, controlled studies have shown the potentially grossly misleading nature of purely subjective responses.

More recent attempts at objectively determining the usefulness of antitussives have included tape recorders as 10 means for capturing sound information concerning coughs emitted by patients. As discussed in Sevelius and Colmore, "Objective Assessment of Antitussive Agents in Patients with Chronic Cough," The Journal of New Drugs 216-23 (July-August 1966), sound information related to coughing can be transmitted to a 15 recorder using a throat microphone taped to a patient. Evaluation of the antitussive includes counting the coughs emitted by each patient, a process conducted by manually reviewing the tape recording for each patient. According to Sevelius and Colmore, although intrusive, the throat microphone 20 and attached wiring does not prevent patients from watching television moving relatively freely throughout a room. Such an intrusive system is, however, likely to disrupt normal sleeping patterns, decreasing both the comfort levels and movement abilities of patients wearing the throat microphones.

25 Other devices presently used for monitoring the onset of coughs often include a belt worn about the abdomen of the patient and sensors maintained in contact with the body. Typical of these devices are those described in U.S. Patent Nos.

30 4,413,620 and 4,240,444 to Tucker and Virgulto, et al., respectively. The patent to Tucker, for example, discloses an abdominal restraint system having a belt designed to inflate in response to signals associated with the onset of coughs. Pressure sensors inserted into the patient using catheters or 35 mounted within the belt are used to detect internal body motion associated with coughing. The apparatus disclosed in Virgulto, et al. similarly includes a belt attached to the patient's body

and uses a protruding, displaceable disc to contact a sealed bulb and change its pressure relative to the atmosphere.

Although both the Tucker and Virgulto, et al. devices respond to the onset of coughing, neither apparatus is designed 5 to evaluate the effectiveness of cough-resisting medications by counting the number of coughs emitted. As with the system of Sevelius and Colmore, the intrusiveness of these devices additionally limits their use as evaluation tools in nocturnal environments. Discomfort felt by patients while wearing the 10 devices is likely to inhibit normal sleeping patterns, thereby decreasing the accuracy of any measurements sought to be made.

U.S. Patent No. 4,848,360 to Palsgard, et al., discloses a less intrusive system used to prevent snoring. According to the Palsgard, et al. patent, a microphone placed 15 beneath the patient's mattress may be used to pass sound information to a series of high- and band-pass filters. The filtered signals subsequently are sent to circuitry designed to measure their periodicity and determine whether the periods correspond to typical time intervals for snore-associated 20 sounds. Once snoring is detected logical signals are transmitted to a counter which activates a vibrational device or other anti-snoring apparatus following receipt of a preselected number of signals.

Like the devices disclosed in the Tucker and Virgulto, et al. patents, the system of Palsgard, et al. is not designed as an evaluation tool for the counting of coughs. The Palsgard, et al. system also lacks storage means beyond the 25 digital counter used to determine if continuous snoring is occurring, preventing any off-line evaluation or visual 30 confirmation of the sleeper's activities. Because some snoring may not alter respiration sufficiently to result in determinable movement by the patient, the system disclosed in Palsgard, et al. similarly lacks any motion detecting means

Summary of the Invention

The cough-counting system of the present invention includes means for providing both movement- and sound-based information obtained from a patient to an analog (or digital) storage device such as a videocassette recorder (VCR). The 5 unintrusiveness of the system, which includes a sensor placed beneath the patient or the patient's mattress, avoids interfering with normal sleeping or waking activities. At the same time, however, audio and visual data derived from both the 10 movements and sounds of the patient increase the accuracy of the cough count and provide means for confirming the count if desired. Storing the data also allows processing to be conducted at any convenient time, further reducing the 15 likelihood of disturbing the patient's sleep.

One embodiment of the present invention includes a pressure transducer, video camera, directional microphone, and VCR having two audio channels. Movement of the patient alters 20 the pressure of an unintrusive, partially inflated air mattress relative to atmospheric pressure, varying the voltage emitted by the associated transducer. The transducer signal then is encoded using modified delta-modulation techniques and signals obtained from the encoder and microphone are transmitted to the two audio channel inputs of the VCR. An infrared light source 25 provides illumination unseen by the patient, allowing the patient's movement to be recorded using the video camera (which may be equipped with an auto diaphragm to extend its dynamic range) connected to the video channel input of the VCR. Part or all of the information stored using the VCR may be fed to 30 signal processing equipment, and the audio track may be frequency filtered to determine the presence and number of coughs. Because the encoded information derived from the transducer frequently is sufficient to generate an accurate 35 cough count, the other audio and video data may be used as confirmation if desired. Additional verification information may be obtained using passive techniques designed to record variations in the patient's infrared energy emissions.

The present system also is capable of developing information relating to respiration and heart rate, functioning as a ballistocardiograph, and determining the presence of symptoms such as restlessness, sleep apnea, cardiac arrhythmia and, in some cases, bed wetting. Each of these conditions manifests itself in differing patient sound, movement, and infrared emission characteristics, allowing the present system to determine its existence through appropriate processing of information such as that available at the audio and visual inputs of the VCR. By examining these conditions the invention may be used to determine the effectiveness of medicines such as sedatives and hypnotics.

It is therefore an object of the present invention to provide a system for counting the number of coughs emitted by a sleeping patient.

It is another object of the present invention to provide a system for evaluating the effectiveness of cough-resisting medications by counting the number of coughs emitted by a medicated patient.

It is an additional object of the present invention to provide an unintrusive system for detecting both sounds emitted by and movement associated with a patient.

It is a further object of the present invention to provide a system using audio and visual information to evaluate the activities of a patient.

It is yet another object of the present invention to provide a system for recording movement- and sound-based audio and visual information for off-line evaluation of the information relating to coughs, heart rate, respiration, cardiodynamics, or other activities of a patient.

Other objects, features, and advantages of the present invention will become apparent with reference to the remainder of the written portion and the drawings of this application.

Brief Description of the Drawings

FIG. 1 is a partially schematic representation of the system of the present invention used to evaluate the activities 5 of a sleeping patient.

FIG. 2 is a schematic representation of an electronic circuit used to encode analog signals obtained in connection with the system of FIG. 1 for subsequent processing.

FIG. 3 is a schematic representation of an electronic 10 circuit used to decode the signals encoded using the circuit of FIG. 2.

Detailed Description of the Drawing

FIG. 1 details the cough-counting system 10 of the present invention. System 10 includes a pressure transducer 14, video camera 18, microphone 22, and storage device 26 such as a VCR, digital worm drive, optical recorder, or other appropriate storage means. Also shown in FIG. 1 are sensor 30, placed beneath a conventional mattress 32 and connected to transducer 14 by connector 34, encoder 38, and infrared light 20 source 42. System 10 is designed to count the number of coughs emitted by a sleeping or waking patient 46, typically a young child but including an adult or an animal, during a preselected interval. By allowing evaluation of both movement- and sound-based data derived from patient 46, system 10 provides an 25 accurate and easily verifiable determination of the amount of coughing which has occurred.

In one embodiment of the present invention, system 10 includes as storage device 26 a VCR having two audio input channels 50 and 54 and a video input 58. Signals derived from 30 a gauge- or piezoelectric-type transducer 14 and a directional microphone 22 are provided to audio inputs 50 and 54 respectively, while information obtained from video camera 18, which may include an auto-diaphragm or -iris to extend its dynamic range, is directed to video input 58. Magnetic tape within the 35 VCR may be used to record the data for subsequent evaluation, allowing off-line processing to be performed at a remote facility. As a result, system 10 may be conveniently used

inside the patient's home, reducing difficulties associated with monitoring patient 46 in a foreign environment.

Before patient 46 retires to bed 62, sensor 30, illustrated in FIG. 1 as an air mattress approximately 24" x 5 36" x 3" in dimension when fully inflated, is placed beneath conventional mattress 32 (or, if desired, beneath patient 46) and inflated to a depth of approximately 1". Partially inflating sensor 30 maintains the air mattress at approximately atmospheric pressure while minimizing the variation in mattress 10 32 firmness experienced by patient 46. At the same time, however, sensor 30 remains sensitive to pressure changes caused by, for example, the coughing, respiration, or heart rate of patient 46. Once patient 46 enters bed 62 a baseline pressure may be determined. The patient's surroundings also may be 15 illuminated by infrared light source 42, allowing infrared recording video camera 18 to function in either the absence or presence of visible light.

Evidence of coughing emitted from patient 46 may be recorded in a variety of ways. As the diaphragm of patient 46 20 moves in response to a cough, pressure deviations at sensor 30 are transmitted to transducer 14. Hollow plastic tubing may be used as connector 34 to transmit air pressure information to transducer 14, although those having ordinary skill in the art will recognize that sensor 30 itself may be a pressure 25 transducer or any other device suitable for measuring movement of patient 46. Transducer 14, in one embodiment having a range of 0-1.5 psi and capable of withstanding 15 psi without calibration shift, converts the differential pressures (relative to atmospheric pressure) into electrical signals for 30 storage on the magnetic tape contained within the VCR or other appropriate storage means used as storage device 26. Because the output of transducer 14 usually falls within a relatively narrow range of values and contains accuracy-reducing noise components, the signal may be passed through a low pass filter 35 (not shown) before being encoded for recording.

Microphone 22 and video camera 18 similarly may record the presence of coughing, with the microphone 22

receiving sound waves emitted by patient 46 and the video camera 18 recording the muscular spasms associated with coughs. Signals from microphone 22 are transmitted to audio input 54 of storage device 26, while the signals from video camera 18 are 5 forwarded to video input 58. A passive infrared system 66, designed to detect variations in the infrared energy emissions of patient 46, may be used to determine the presence of coughing as well.

Encoder 38 (FIG. 2), designed to encode the analog 10 signal from transducer 14 in serial form, includes a comparator 70, flip-flop 74, fixed delay generator 78, resistor ("R₁"), and capacitor ("C₁"). An analog signal, which may be the output of transducer 14 and in some embodiments has a bandwidth of 0-2.5 Hz, is transmitted to the positive terminal ("+") of 15 comparator 70. The output of comparator 70 then is strobed into the input ("D") of flip-flop 74 with each clock pulse ("CLOCK"), and the output value ("Q") of flip-flop 74 is sent through fixed delay generator 78 back to the reset terminal ("RE") of flip-flop 74. The output value ("Q") of flip-flop 74 20 also serves as the output of encoder 38, and is fed back to the negative terminal ("−") of comparator 70 through resistor ("R₁") and capacitor ("C₁"). As illustrated in FIG. 2, the set terminal ("S") of flip-flop 74 is grounded. In addition, choosing 5kHz for the "CLOCK" frequency and 10Hz for R₁C₁ (i.e. 25 the product of "R₁" multiplied by "C₁") makes pulse recovery relatively easy during processing and reduces tracking error substantially.

Encoder 38 performs a modified form of delta modulation. Traditional delta modulation includes comparison of an 30 input signal to the average value of the system output, with the result of the comparison being clocked into a flip-flop. The output of the flip-flop also serves as the system output, which is averaged using an RC circuit and transmitted back to the positive terminal of the comparator. The system output 35 consists of a square wave having transitions synchronous with the clock pulses, with the input information encoded in the transitions which do and do not occur. Although traditional

delta modulation serves as a useful technique for encoding analog signals in serial form, its large bandwidth requirements, resolution limitations, and inability to compensate for output data recovery drift diminish its effectiveness in connection with system 10 of the present invention. By modifying traditional circuitry to, among other things, include fixed delay generator 78, however, encoder 38 may compensate for such output drift and allow the output ("Q") of flip-flop 74 to maintain fidelity for all values from D.C. to 2.5 Hz at the comparator 70 input.

An important feature of encoder 38 is that it allows processing to begin at any point in the data stream, as the recovered information will converge to the correct input values with a time constant of $10R_1C_1$. FIG. 3 details a circuit 82 for recovering the input data, which includes fixed duration pulse generator 86 and a resistor ("R₂") and capacitor ("C₂") network. The output of circuit 82 then may be appropriately processed to determine the quantity of coughs emitted (or other quantifiable behavior performed) by patient 46 during a specified interval.

The foregoing is provided for purposes of illustration, explanation, and description of embodiments of the present invention. Modifications and adaptations to these embodiments will be apparent to those of ordinary skill in the art and may be made without departing from the scope or spirit of the invention. In particular, system 10 may be used to detect and evaluate information relating to respiration, heart rate, and various other types of motion and activities of patient 46, and may function as a ballistocardiogram. Moreover, sensor 30 may comprise a variety of multi-chambered air mattresses, depending on the type of patient 46 behavior desired to be measured. Single chambered mattresses allow air to move freely within the total volume enclosed, permitting transducer 14 to provide an accurate reflection of deviations in the total load on sensor 30. If measurements of more localized activity, such as various types of patient motion (including, for example, propping on an elbow) are desired,

however, the single-chambered air mattress could be replaced with one having a number of seams extending much of the length or width of the mattress, thereby dividing it into narrow channels. The seams would prevent rapid equilibrium within the 5 mattress and allow local transient pressure to be sensed at the output pressure port. Similarly, if localized data sensitivity is desired in addition to overall load pressure, the multi-chambered mattress could be designed to include seams extending virtually its entire width or length (but not completely 10 sealing any channel from the others), with pressure ports placed in each channel, and separate transducers employed to allow outputs to consist of individual measurements or "summary" recordings based on, for example, weighted sum and difference measurements.

15

We claim:

1. A system for evaluating activities of a patient
2 based on the patient's movement, comprising:
 - 3 a. means for sensing pressure changes caused by
4 the movement;
 - 5 b. means for storing the sensed changes; and
 - 6 c. means for evaluating the patient's activities
7 based on the stored changes.
1. 2. A system according to claim 1 in which the
sensing means comprises a pressure transducer.
1. 3. A system according to claim 1 in which the
storing means comprises a recorder.
1. 4. A system according to claim 1 further comprising
2 means for encoding the sensed changes.
1. 5. A system according to claim 1 further comprising
2 means for sensing sounds emitted by the patient.
1. 6. A system according to claim 1 further comprising
2 means for sensing video information related to
3 the patient's movement.
1. 7. A system according to claim 2 in which the
2 sensing means is remote from the patient and
3 further comprises an air mattress having at least
4 one chamber.
1. 8. A system according to claim 3 in which the
2 recorder comprises a videocassette recorder
3 having a plurality of audio channel inputs.
1. 9. A system for counting coughs emitted by a patient
2 recumbent upon a mattress, comprising:
 - 3 a. an air mattress positionable beneath the
4 mattress for sensing pressure changes caused
5 by the emitted coughs;
 - 6 b. a pressure transducer connectable to the air
7 mattress for converting the pressure changes
8 to a first series of electrical signals;
 - 9 c. a microphone remote from the patient for
10 sensing sounds caused by the emitted coughs
11 and converting the sounds to a second series
12 of electrical signals; and

1 / 1

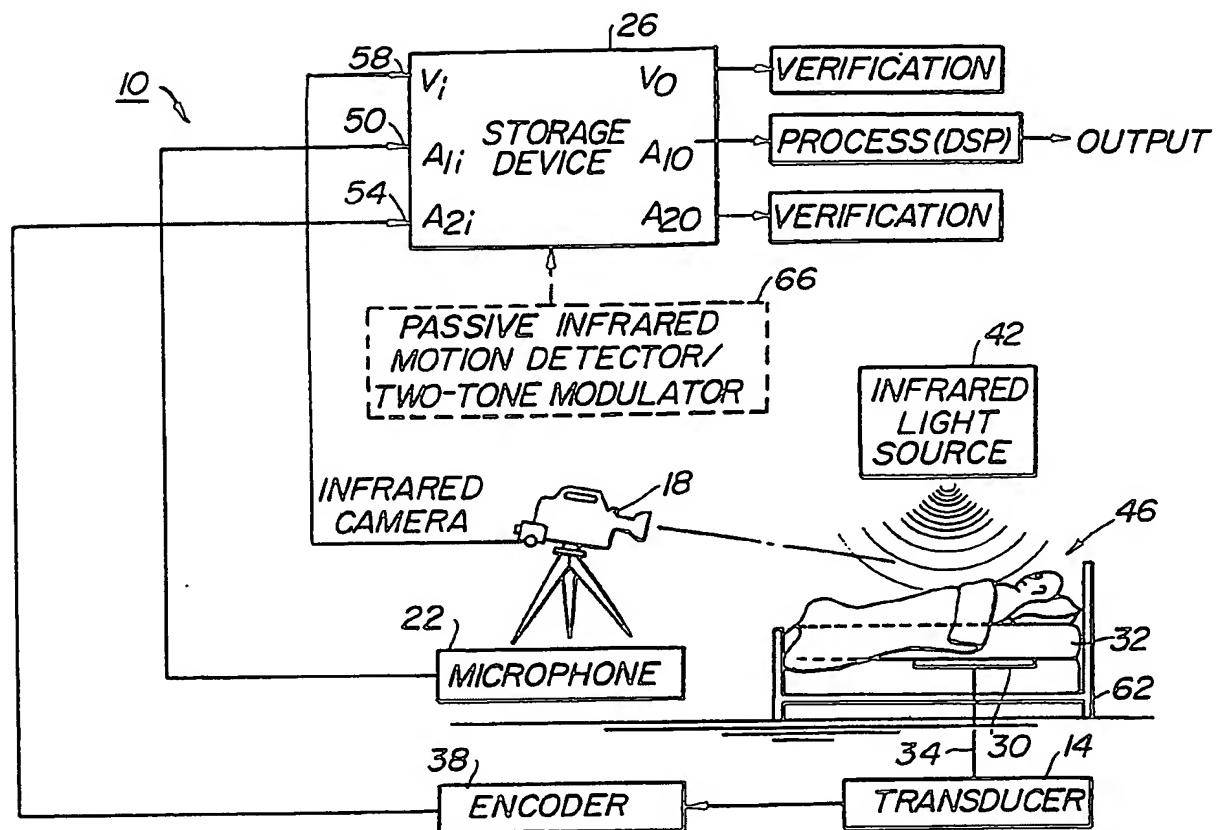


FIG. 1V

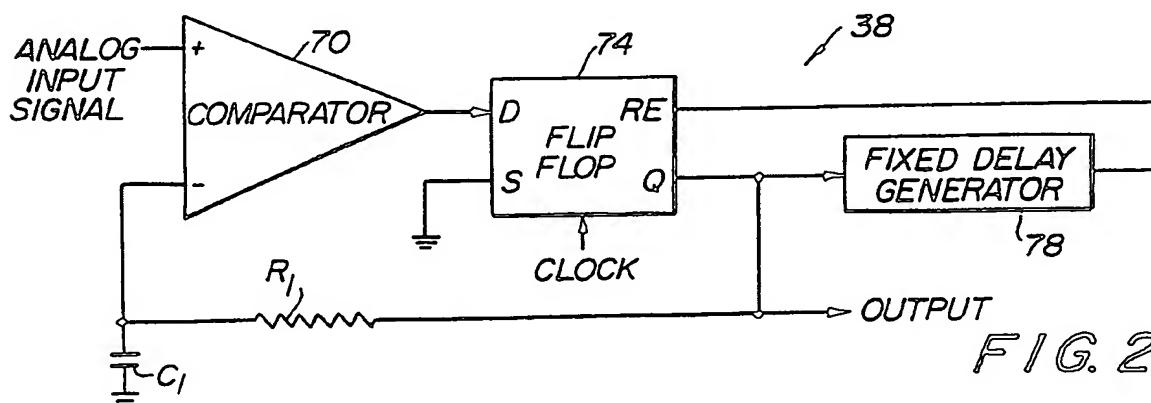


FIG. 2

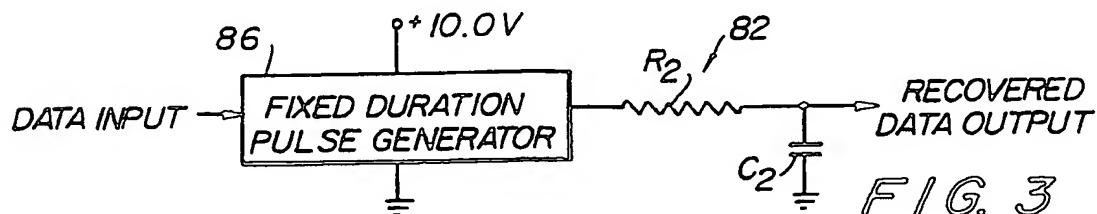


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/02707

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶

According to International Patent Classification (IPC) or to both National Classification and IPC
 IPC(5): A61B 5/103
 U.S. CL.: 128/782

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

Classification System	Classification Symbols
U.S.	128/721, 671, 782, 715, 773

Documentation Searched other than Minimum Documentation
 to the Extent that such Documents are Included in the Fields Searched ⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4,813,436 (AU) 21 March 1989, See entire document.	1-4,6,14
A	US, A, 4,320,766 (ALHANKA) 23 March 1982, See abstract.	1-18
A	US, A, 4,848,360 (PALSGARD) 18 July 1989, See abstract.	1-18
A	US, A, 4,657,026 (TAGG) 14 April 1987, See abstract.	1-18
A	US, A, 4,240,444 (VIRGULTO) 23 December 1980, See abstract.	1-18

* Special categories of cited documents: ¹⁰

"A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier document but published on or after the international filing date
 "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

15 JULY 1991

Date of Mailing of this International Search Report

13 AUG 1991

International Searching Authority

ISA/US

Signature of Authorized Officer

Andrea Robinson
SCOTT GETZOW

See notes on accompanying sheet